

Attorney Docket No. 120785.00311  
Serial No. 10/670,490  
Inventor: Barnea  
Paper dated May 30, 2007

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### REMARKS

Applicants' attorney wishes to thank the Examiner for the careful attention given the present application. Claims 9-22 and 25-30 are pending. Claims 1-8, 23 and 24 were previously canceled. Claims 9, 15, 22 and 25 are amended herein. New claims 26-30 are added. Support for the amendments is found in the specification at, for example, page 3, lines 28-31, page 11, lines 29-30, page 12, lines 10-12, page 26, line 29 to page 27, line 13, Figure 9.

#### 35 U.S.C. § 112, first paragraph: written description

The Examiner has rejected claims 9-22 and 25 under 35 U.S.C. § 112, first paragraph for purportedly failing to comply with the written description requirement. Applicants respectfully disagree. Regarding claims 22 and 25, the Examiner argues that the claim encompasses larger peptides and one of skill in the art would conclude that Applicants were not in possession of the genus of peptides consisting of SEQ ID NO:1-12. Applicants respectfully submit that the claims fully comply with the written description requirement. Applicants respectfully request that the rejection be withdrawn.

#### 35 U.S.C. § 112, first paragraph: enablement

The Examiner has rejected claims 9-22 and 25 under 35 U.S.C. § 112, first paragraph as not enabled by the specification. The Examiner argues that only SEQ ID Nos. 2, 3 and 8 have such activity. Applicants respectfully disagree. Figure 9 provides results from antiproliferation assays for 12 peptide fractions. As discussed in the specification at page 27, fractions a, f and k demonstrate the greatest levels of antiproliferative activity. The remaining fractions in Figure 9 all show antiproliferative activity as compared to the negative control.

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Claims 22 and 25 are directed to isolated peptides and are fully enabled by the specification. As discussed above, the application has shown these to have antiproliferative activity and one of skill in the art would understand how to use the claimed peptides. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

35 U.S.C. § 102(e)

Introduction

The Examiner has rejected claims 9-11, 14, 22 and 25 under 35 U.S.C. § 102(e) as anticipated by Barnea (U.S. Patent No. 5,648,340) ("Barnea"). Applicants respectfully disagree.

As a preliminary matter, Barnea does not explicitly disclose isolated peptides, compositions comprising isolated peptides, or methods of using isolated peptides of the present claims. Barnea does not teach an isolated peptide as would be understood by one of ordinary skill in the art (*see* MPEP 2144.04). Barnea's extract is a mixture of all proteins and peptides of 8 kDa or less. By contrast, the peptides of the present claims are isolated, that is, separated from other components such that their activity can be measured. *See, e.g.*, the present specification at page 26, line 11 to page 27, line 13. This difference is emphasized in the present claim language that recites *isolated* peptides. For example, Barnea does not disclose isolated peptides as presently recited in claims 22, 25, and 30.

The Examiner argues that the embryonic fraction of molecular weight of less than 8 kDa inherently anticipates the peptides of claims 22 and 25 and that Barnea also teaches a method of treating various cancers and teaches the less than 8 kDa fraction in a pharmaceutically acceptable carrier. Applicants respectfully disagree. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing

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described in the reference, and that it would be so recognized by persons of ordinary skill.

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' ” In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999) (emphasis added)(citations omitted); MPEP 2112.

Applicants discuss the applicability of the Examiner's rejection in reference to the various claims in the sections that follow.

#### Composition Claims

Barnea does not inherently disclose the isolated peptides and compositions of claims 22 and 25 and 28-30. In particular, Applicants direct the Examiner's attention to the language of new claims 28 and 29 reciting that the peptide exhibits an antiproliferative activity. The Examiner references Table III showing an antiproliferative effect of a less than 8 kDa fraction to support the proposition that the less than 8 kDa fraction inherently contains the claimed peptides. Although Barnea's less than 8 kDa fraction may contain one or more peptides, it is not certain that any of the Barnea extracts would have included the presently claimed peptides. In fact, it does not appear that Barnea even remotely describes any of the claimed peptides. In point of fact, while the less than 8 kDa fraction demonstrates antiproliferative activity, the less than 3 kDa fraction does not. Since the less than 3 kDa fraction of Barnea does not show an antiproliferative effect, how can Barnea be said to show a peptide of the present invention with an antiproliferative activity? Barnea suggests, rather, that the peptides of the present claims are not at all found in the Table III extracts, because if they were, one would expect the less than 3 kDa fraction to also demonstrate antiproliferative activity.

Additionally, Barnea uses human embryonic spinal cord to prepare the tested extracts. This is different from the material used in the present application, wherein the peptides

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were isolated from porcine embryonic liver. That is, not only does Barnea use a different species to prepare a fraction of 8 kDa or less, he also uses a developmentally different portion of the embryonic tissue. It cannot be said for certain, therefore, that the relatively unpurified Barnea extracts even contain the claimed peptides.

Thus, Barnea does not teach, either explicitly or inherently, the presently claimed peptides. Accordingly, Applicants respectfully request reconsideration and withdrawal of the Examiner's rejection.

#### Method Claims

With regard to the method claims, the Examiner's argument is even more difficult. The method claims 9-11 and 14, and new claims 26 and 27 are not inherently anticipated by Barnea because Barnea does not teach either explicitly or inherently all elements of the claims. The Examiner references Table III showing an antiproliferative effect of a less than 8 kDa fraction to support the proposition that the less than 8 kDa fraction inherently contains the claimed peptides. First, Barnea does not disclose the isolated peptides of the present claims, as discussed above, and so cannot disclose methods of inhibiting proliferation using the claimed peptides. Additionally, even if, *arguendo*, Barnea's extract did contain an approximately 820 Da peptide, Barnea does not show a method of inhibiting proliferation of cancer cells by administering an effective amount of peptide as claimed. Rather, Barnea shows an antiproliferative effect from a less than 8 kDa fraction, but shows no antiproliferative effect from a less than 3 kDa fraction. Thus, any antiproliferative effect shown in Barnea appears to be due to a component that is absent from the less than 3 kDa fraction. The Examiner has presented no evidence to prove that the claimed peptides are present in the less than 8 kDa fraction, particularly where they appear to be absent from the less than 3 kDa fraction. Further, the

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antiproliferative activity of the less than 8 kDa fraction may have been caused by any number of proteins, peptides or other molecules found in that relatively unpurified mixture. Thus, the Barnea does not describe, either explicitly or inherently, a method of inhibiting proliferation by administering an effective amount of at least one claimed peptide. Applicants respectfully request that the rejection be withdrawn.

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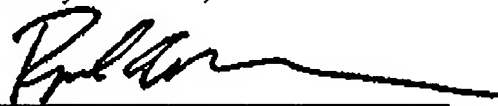
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CONCLUSION

It is believed that the pending claims are in condition for allowance and notice to such effect is respectfully requested. The Commissioner is hereby authorized to charge deposit account No. 50-0436 for any additional fees that may be due in connection with this response.

Should the Examiner have any questions regarding this application, the Examiner is invited to initiate a telephone conference with the undersigned.

Respectfully submitted,

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Dated: May 30, 2007

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